CardioChek®

Brand Analyzers Portable Whole Blood Test System User Guide

For Self-Testing Use

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I. INTRODUCTION

Thank you for selecting a CardioChek® analyzer from Polymer Technology Systems, Inc. (PTS, Inc.).

The CardioChek analyzer is a fast, portable, and reliable whole blood analyzer. The CardioChek test system includes an analyzer and separately available CardioChek test strips/MEMo Chip®. This test system is intended for *in vitro* diagnostic use to test whole blood. Using this test system, you can quickly measure various blood components from a small sample size. The CardioChek test system is capable of screening lipids (including Cholesterol, HDL Cholesterol, and Triglycerides) and testing for diabetes and other disease states.

The CardioChek analyzer uses reflectance photometry for testing. The analyzer reads color changes that occur on a test strip after blood is placed on the test strip.

Before you begin testing, please read this entire User Guide and the test strip package insert completely. This provides the necessary information for the use of this test system. Please remember to return the enclosed warranty card to ensure you receive product updates.

For questions or assistance with your CardioChek test system, please contact PTS, Inc. using the following contact information:

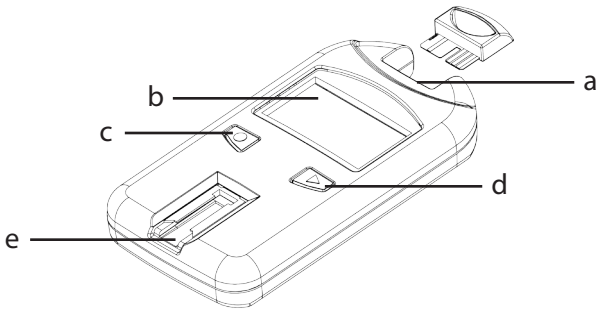
Polymer Technology Systems, Inc.
7736 Zionsville Road
Indianapolis, IN 46268 USA
+1-317-870-5610 (Direct)
+1-877-870-5610 (Toll-free inside the US)
inforequest@cardiochek.com (E-mail)
www.cardiochek.com

Hours: 8:00 a.m. - 8:00 p.m., US Eastern Standard Time, Monday-Friday.

II. INTRODUCTION TO THE CARDIOCHEK TEST SYSTEM

The CardioChek® Test System

The CardioChek test system consists of three main parts. These include the analyzer, CardioChek test strips and a MEMo Chip®. When a blood sample is applied to the test strip, a chemical reaction occurs producing a color change. The analyzer measures the color reaction and compares the information to the calibration curve stored in the MEMo Chip. The analyzer converts this color reading into a test result that is displayed on the screen.



MEMo Chip Port (a)

The MEMo Chip port is located at the top of the analyzer.

Display (b)

Display shows test results, messages, time, date, and stored results.

ENTER Button (c)

Press this button to turn the analyzer ON or to accept the current menu choice.

NEXT Button (d)

Press this button to turn the analyzer ON or to advance to the next menu option.

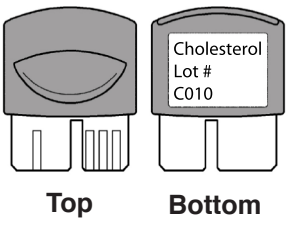
Test Strip Insert Opening (e)

The test strip insert opening is positioned in the lower front of the analyzer. The test strip is inserted here with the raised lines facing up.

II. INTRODUCTION TO THE CARDIOCHEK TEST SYSTEM, continued

The MEMo Chip®

Each package of CardioChek® test strips contains a color-coded MEMo Chip. The color-coded MEMo Chip contains the settings for each test. The top of the MEMo Chip has a finger notch. The bottom has a label with the test name and lot number. Always make sure you insert the MEMo Chip into the port with the finger notch facing up.



MEMo Chip (Top and Bottom)

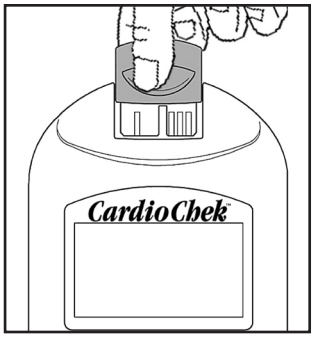
What does the MEMo Chip do?

- Reads the test strip expiration date
- Tells the analyzer which test(s) to run
- Contains the calibration curve and the lot number for the specific test strip lot
- Controls test sequences and timing
- Establishes the measuring range for the test

Guidelines for using the MEMo Chip

- The MEMo Chip must be in place to run a test.
- Use only the MEMo Chip that is included with each package of test strips. The lot number code on the test strip vial, MEMo Chip and analyzer display must match.
- If the expiration date in the MEMo Chip has expired, the analyzer will display EXPIRED LOT.
- If your MEMo Chip is lost or missing, please call PTS, Inc. Customer Service for a replacement.

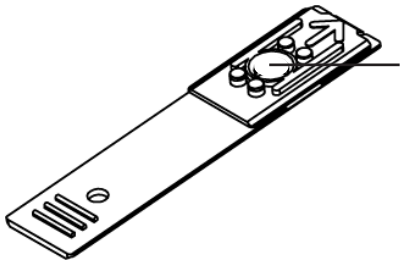
II. INTRODUCTION TO THE CARDIOCHEK TEST SYSTEM, continued



The MEMo Chip® port is located at the top center of the analyzer. The MEMo Chip is inserted into this port with the finger notch facing up. Push firmly, but gently, until the MEMo Chip is fully inserted. **Important:** Be careful not to bend the connector.

Test Strip

To test blood on the CardioChek® analyzer, use test strips specific for each test. A test strip is inserted into the analyzer, then blood is applied to the blood application window. A chemical reaction occurs producing a color change. The analyzer measures the color reaction and compares the information to the calibration curve stored in the MEMo Chip. The analyzer converts this color reading into a test result, displayed on the screen. Each CardioChek test strip box contains a package insert that provides instructions for use and information specific for each test. Please read the instructions completely before testing.



Blood Application Window

CardioChek test strip

III. SETUP

Battery Use and Replacement

The CardioChek® analyzer requires two (2) AAA 1.5 volt high quality alkaline batteries.

When to Replace the Batteries

The analyzer will give you an indication on the display that the batteries need to be changed. When the display reads CHANGE BATTERY, no more tests can be run until the batteries are changed. Always replace the batteries with high quality alkaline batteries. It is recommended to keep a spare set of batteries on hand. To extend battery life, remove the test strip as soon as a result is displayed. The time/date and results stored in memory will not be erased when the batteries are changed.

How to Install/Replace the Batteries:

1. Open the battery door on the back of the CardioChek analyzer by pressing and sliding it in the direction of the arrow (toward the MEMo Chip® port).
2. Remove old batteries from the compartment and safely discard.
3. Insert the new batteries into the battery compartment with the positive (+) terminal facing to the left on the top battery, and to the right on the bottom battery as marked on the inside compartment.
4. Replace the battery door. To make sure the batteries were installed correctly, push either of the two buttons on the front of the analyzer to turn the CardioChek analyzer ON.

WARNING! Dispose of the old batteries properly.

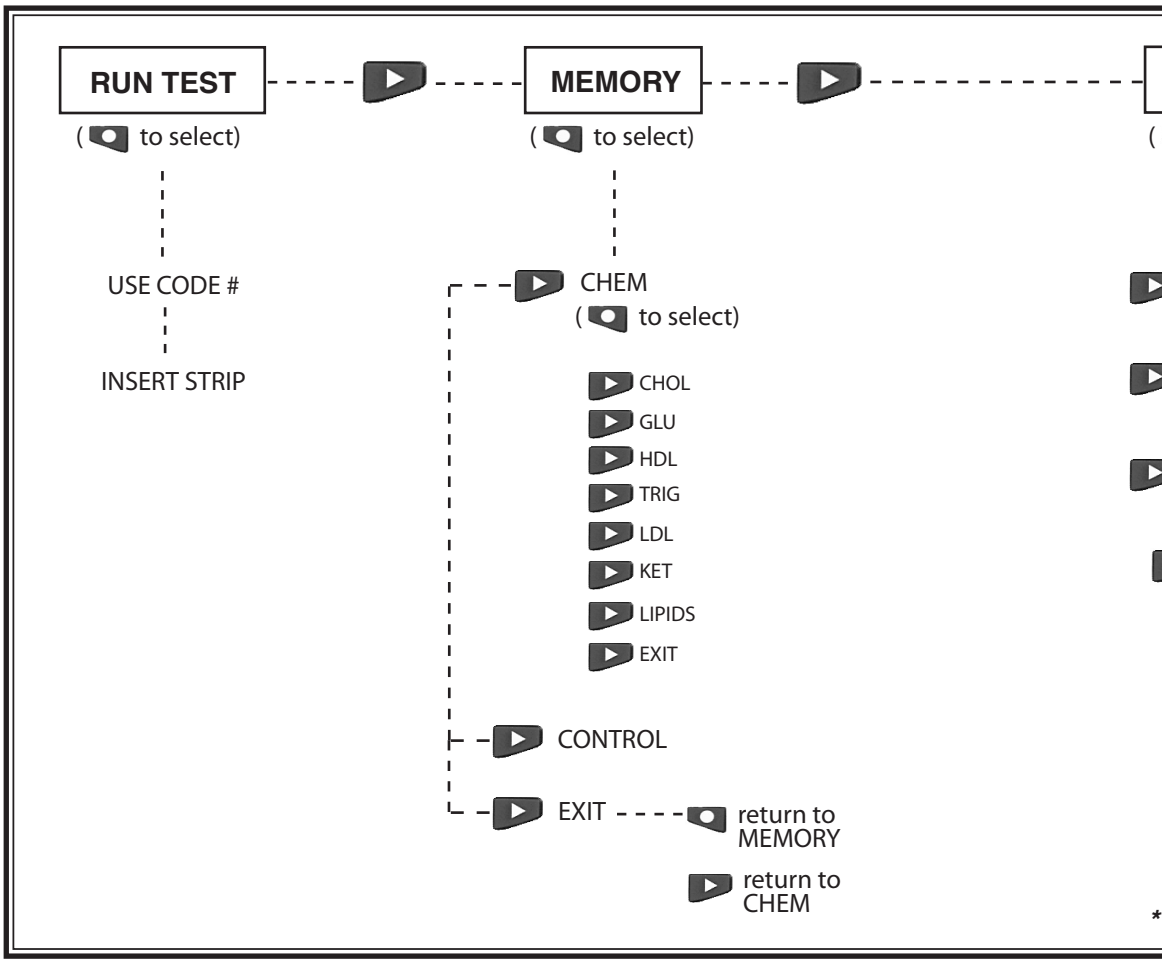
III. SETUP, continued

CardioChek® System Menus

This diagram provides a layout of the menus within the CardioChek analyzer. Detailed information on the use of each menu follows in this section of the User Guide.

Buttons

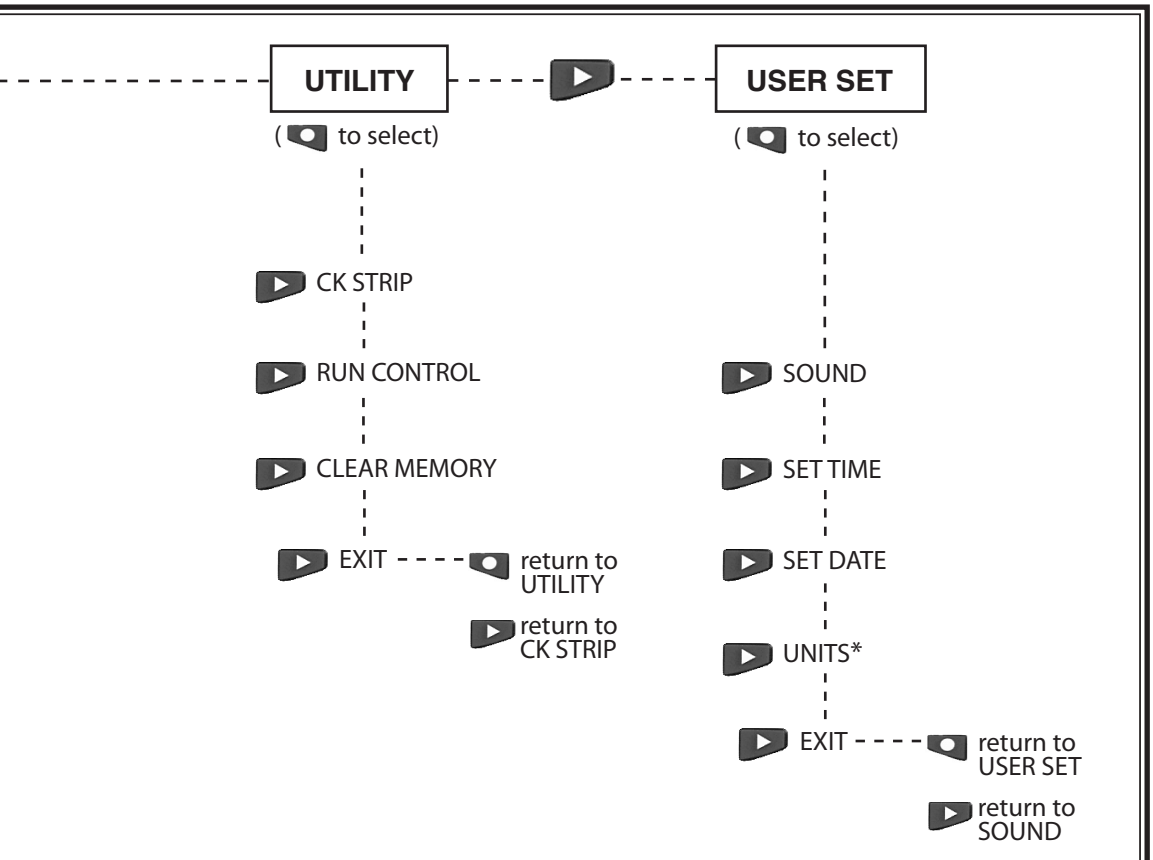
ENTER Button: Press this button to turn the analyzer ON or to accept the current menu choice.



III. SETUP, continued

NEXT ▶ Button: Press this button to turn the analyzer ON or to advance to the next menu option.

- Hold ● and ▶ down at the same time to shut off the analyzer from one of the main menus (RUN TEST, MEMORY, UTILITY, or USER SET).



**** Units may be locked, and therefore UNITS will not appear.***

III. SETUP, continued

How to Turn the Analyzer OFF

To turn the analyzer OFF press both buttons at the same time for three seconds at any of the following Main Menu headings: RUN TEST, MEMORY, UTILITY, or USER SET.
After three minutes of idle time (without a test strip or check strip inserted) the analyzer will perform a 10 second count down and turn OFF. To stop shutdown press either button.
You can also remove the batteries to turn the analyzer OFF.

The first time the analyzer is turned on you will be required to set the language, date, and time.

Setting Language

The language menu consists of the following choices:
English (ENGLISH), Spanish (ESPANOL),
Italian (ITALIANO), German (DEUTSCH),
French (FRANCAIS), Portuguese (PORTUGSE), and
Dutch (NEDERL).

How to Set the Language:

1. Turn the analyzer ON by pressing either button (Enter or Next).
2. The display will read LANGUAGE. Press Enter.
3. ENGLISH will be displayed. Press Enter if English is desired.
4. For other languages press Next until the desired language is displayed, then press Enter. To set the time proceed to **How to Set the Time.**

III. SETUP, continued

How to Reset the Language:

1. Allow the analyzer to automatically turn OFF or remove the batteries and replace them.
2. Press and hold Enter down for approximately 5 seconds during the analyzer power-up stage until LANGUAGE is displayed.
3. Press Enter. Press Next to scroll through the language choices.
4. Press Enter to select the language that is displayed. SET TIME will be displayed.

How to Set the Time:

1. If the analyzer is OFF, press either button to turn the analyzer ON. Wait for the display to read either INSTALL MEMO CHIP (if a current MEMo Chip is not installed) or INSERT STRIP (if a current MEMo Chip is installed). Press Enter. The display will read RUN TEST.
2. Press Next until USER SET is displayed.
3. Press Enter. Press Next until SET TIME is displayed.
4. Press Enter and the clock format is displayed: 12/24 HR.
5. Press Next to alternately display the 12 hour AM/PM clock or the 24 hour clock. Press Enter to accept the displayed clock format. The display will read HOUR and the numerical hour. If 12 hour clock was chosen, AM/PM appears in the upper right hand corner of the display.
6. Press Next to increment the hour.
7. Press Enter to accept the displayed hour. The display will read MINUTE and the numerical minute.
8. Press Next to increment the minutes.

III. SETUP, continued

How to Set the Time, continued:

9. Press Enter to accept the displayed minute. The display will read SET TIME. To set the date, proceed to **How to Set the Date** - Step 4.
10. To exit, press Next until EXIT is displayed. Press Enter.
11. Press Next to return the display to RUN TEST.

How to Set the Date:

1. If RUN TEST is displayed, go to Step 3. If the analyzer is OFF, press either button to turn the analyzer ON. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.
2. Press Next. The display will read RUN TEST.
3. Press Next until USER SET is displayed. Press Enter.
4. Press Next until SET DATE is displayed.
5. Press Enter and the numerical month is displayed.
6. Press Next to increment the month.
7. Press Enter to accept the displayed month. The display will read DAY and the numerical day of the month.
8. Press Next to increment the day.
9. Press Enter to accept the displayed day. The display will read YEAR and the numerical year.
10. Press Next to increment the year.
11. Press Enter to accept the displayed year. The display will read SET DATE. To set the units, proceed to UNITS.
12. Press Next until EXIT is displayed. Press Enter.
13. Press Next to return the display to RUN TEST.

III. SETUP, continued

How to Set the Units:

The CardioChek® analyzer may be shipped with preset units.

NOTE:

- If the USER SET menu does not display "UNITS" the instrument is locked in preset units
- The units cannot be changed if the system has been locked
- To confirm current configuration of the analyzer's units run a check strip in the RUN TEST mode and observe the units that are displayed

If your analyzer's units have not been preset, follow the steps listed below to change your units to mg/dL, mmol/L, or g/L:

1. If RUN TEST is displayed, go to Step 3. If the instrument is OFF, press either button to turn the analyzer ON. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.
2. Press Enter. The display will read RUN TEST.
3. Press Next until USER SET is displayed.
4. Press Next until UNITS is displayed. If UNITS is not shown on the display, the units on this instrument have been locked and cannot be changed. If UNITS appears on the display screen, proceed to the next step.
5. Press Enter. The display will read mg/dL. If mmol/L or g/L is desired press Next until the desired unit appears on the display screen.

III. SETUP, continued

How to Set the Units, continued:

6. Press Enter to select the desired units. The display will then read UNITS.
7. Press Next until EXIT is displayed.
8. Press Enter to return to USER SET.
9. Press Next to return to RUN TEST.

How to Set the Sound:

The CardioChek® analyzer sound has been preset to BEEP ON. To turn the sound on or off please follow the steps listed below:

1. If RUN TEST is displayed, go to Step 3. If the analyzer is OFF, press either button to turn the analyzer ON. Wait for the display to read INSTALL MEMO CHIP or INSERT STRIP.
2. Press Next. The display will read RUN TEST.
3. Press Next until USER SET is displayed.
4. Press Enter, then Next until SOUND is displayed.
5. Press Enter. The display will read BEEP ON or BEEP OFF.
6. Press Next to select either BEEP OFF or BEEP ON.
7. Press Enter to accept the sound choice displayed.
8. Press Next until EXIT is displayed.
9. Press Enter to return display to USER SET.
10. Press Next to return to RUN TEST.

IV. CHECKING THE SYSTEM

Instrument Check Strip

A gray instrument check strip (included in the analyzer carrying case) can be used to verify proper functioning of the CardioChek® analyzer's electronic and optical systems. The check strip provides a color standard read by the analyzer. When the check strip is not in use, please store it in the analyzer carrying case. It is recommended that you check your analyzer with the check strip when:

- You first receive it
- You drop the analyzer
- You get a result that is not expected

How to Use the Instrument Check Strip:

1. Turn the analyzer ON by pressing either button.
2. When INSTALL MEMO CHIP or RUN TEST is displayed, press Next until UTILITY is displayed. Press Enter.
3. Press Enter when CK STRIP is displayed.
4. Hold the check strip at base of strip and insert the check strip, ribbed side up, into the test strip insert opening when INSERT STRIP is displayed.
5. The analyzer should display PASSED. (If the display reads FAILED, see the note at the end of this section.) Remove the check strip and store it in the analyzer carrying case.
6. Press Next until EXIT is displayed. Press Enter.
7. Press Next until RUN TEST is displayed.
8. Press Enter. The analyzer is ready to run tests.

IV. CHECKING THE SYSTEM, continued

Note: If the analyzer displays FAILED:

1. Clean the CardioChek® analyzer test strip insert opening (where the strip is inserted into the analyzer). See the Care and Cleaning section.
2. Inspect the check strip to make sure it is not dirty or damaged. Use the spare check strip and repeat.
3. See the Troubleshooting section.

Quality Control

Controls (also known as "Quality Control materials") are solutions for which an expected analyte concentration range has been established. Controls are tested to check the performance of your test system: CardioChek analyzer, MEMo Chip®, and test strips. Use Quality Control materials provided by PTS, Inc.

PTS Panels® Multi-Chemistry Controls	REF 721
PTS Panels® HDL Controls	REF 722

Refer to control package insert for control specifications.

Healthcare professionals testing with this system should follow their facility's guidelines and policies regarding the use of Quality Control materials.

IMPORTANT: Do not use control solutions that have expired. Check the expiration date printed on the control bottles.

For performing a Quality Control test, see Section V. CONTROL TESTING.

To perform a control test you need:

- CardioChek analyzer
- CardioChek test strips
- Quality Control materials
- Quality Control instructions
- Quality Control range insert

V. CONTROL TESTING

Control Testing

Control testing, also known as Quality Control testing, is used to ensure all the parts of the test system are working properly together and the test results are accurate and reliable within the limits of the system. A Quality Control material, or control, is a liquid containing an analyte known to be within a certain range. This range is supplied with the Quality Control material or is available online at www.cardiochek.com. Home users should perform control testing with each new test strip lot, and whenever it has been more than a month since using that lot of test strips.

How To Run a Quality Control Test:

1. Install the correct MEMo Chip® for the lot of strips that you are using.
2. Press either button to turn the analyzer ON.
3. Press Next until the display reads UTILITY. Press Enter.
4. Press Next until RUN CONTROL scrolls across the display. Press Enter.
5. Insert the test strip into the analyzer. The CardioChek® analyzer will display APPLY SAMPLE. This indicates the system is ready for a sample (control) to be applied. Immediately replace the vial cap, making sure the strip vial is closed tightly.
6. Remove cap from the Quality Control material and turn bottle upside down.

   CONTROL MUST BE APPLIED TO TEST STRIP WITHIN 10 SECONDS OF REMOVING THE STRIP FROM THE VIAL.

V. CONTROL TESTING, continued

7. Hold bottle directly over and perpendicular to the blood application window on the test strip.
8. Squeeze bottle so a small drop of control solution is formed.
9. Allow the drop of control solution to fall onto the application window of the test strip. Do not allow the tip of the bottle to touch the test strip.
10. Replace cap on the Quality Control material.
11. During testing CONTROL is displayed. Results will be displayed within about one to two minutes.
12. Compare control results to the values on the Quality Control range insert included with Quality Control materials.
13. The control result(s) will also be stored in the analyzer's memory.
14. To exit the control testing menu press Enter twice. RUN CONTROL will be displayed.
15. Press Next until EXIT is displayed. Press Enter.
16. Press Next until RUN TEST is displayed.

If Quality Control Results are Not in Range:

1. Ensure test strip insert opening area is clean.
2. Make sure neither the test strips nor the controls are past the expiration date printed on the label.
3. Make sure the MEMo Chip® matches the test strip lot.
4. Repeat the test again using fresh materials.
5. Call PTS, Inc. Customer Service for assistance.

VI. RUNNING A TEST

Blood Testing

A test strip package insert is included with each box of test strips. Please read the test strip package insert along with this section of the User Guide completely and carefully before testing.

Testing Supplies

To perform a blood test you need:

- CardioChek® analyzer
- CardioChek test strips
- Lot specific MEMo Chip®
- Sterile lancet
- Capillary blood collector or pipet
- Gauze or cotton balls
- Alcohol wipe (optional)

This analyzer requires whole blood for testing. Do not operate the analyzer in direct light. Reference the Care and Cleaning section for more information.

Helpful Hints on Getting a Good Drop of Blood:

1. Warm the fingers to increase blood flow.
2. Let the arm hang down at the person's side briefly to allow blood flow to the finger tips.
3. Instruct the patient to wash hands in warm, soapy water. Rinse well and dry completely. If an alcohol wipe is used, let the finger air dry before testing.

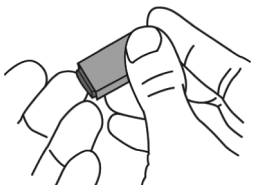
VI. RUNNING A TEST, continued

How to Obtain a Blood Sample:

To perform a fingerstick:

1. Clean the finger. Be sure the finger is completely dry.
2. Use a new sterile, disposable lancet to puncture the skin.
3. Stick the finger on the side of the fingertip, instead of the center. See picture below:

CORRECT WAY TO
STICK THE FINGER



4. To get a drop of blood, gently apply pressure to the finger starting at the end of the finger closest to the hand and moving towards the tip. Wipe away the first drop of blood with gauze and use the second blood drop for testing. The blood drop should be hanging down from the finger to make it easier to collect the sample with a capillary pipet or plastic blood collector.
5. Follow the specific instructions found in the test strip package insert for each test for sample application and volume ranges. Use of capillary pipet or plastic blood collector ensures a sufficient volume of blood has been applied to the test strip.
6. Make sure the test strip is inserted all the way into the test strip insert opening.
7. Use the test strip and lancet one time only. Dispose of properly.

VI. RUNNING A TEST, continued

How to Run a Test:

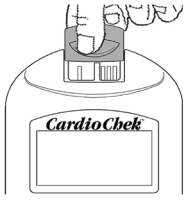
1. Insert correct MEMo Chip® for the lot of strips in use.
2. Insert MEMo Chip with finger notch (top) side up, lot number code facing down.
3. Turn CardioChek® analyzer ON by pressing either button.
4. When INSERT STRIP is displayed, insert the test strip into the analyzer as far as it will go.
5. Obtain a blood drop following the correct technique.
6. When APPLY SAMPLE is displayed, apply blood to the test strip. Refer to each specific test strip package insert for sample volume and sample application instructions.
7. Within one to two minutes, the results will be displayed.
8. Remove test strip and discard.
9. The analyzer automatically shuts down after three minutes of idle time with no test strip inserted.

IMPORTANT: Do not leave a used test strip or check strip in the analyzer test strip opening. This prevents the analyzer from automatically shutting down and shortens battery life.

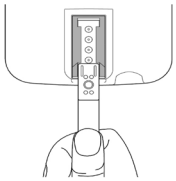
VI. RUNNING A TEST, continued

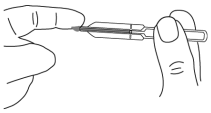
Quick Reference Testing Guide

1. *Insert MEMo Chip® with lot number that matches test strip vial lot number. Press either button to turn the CardioChek® ON. Analyzer will display lot code.*

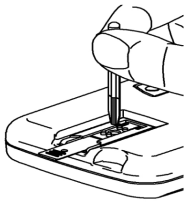


2. *When INSERT STRIP is displayed, hold by the raised lines and insert test strip into the analyzer as far as it will go.*

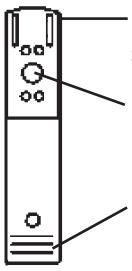




3. *When APPLY SAMPLE is displayed, apply whole blood* sample with a capillary pipet to blood application window.*



4. *Within two minutes the result will appear on the display. Remove and <u>discard strip</u>. Do not add more blood to a test strip that has been used.*



CardioChek test strip

* *Refer to each specific test strip package insert for sample volume and sample application instructions.*

VII. RESULTS

Results for each test are in units of measure specific to each test and your location. The measuring range for each test is listed in the test strip instructions. This is the range that your CardioChek® analyzer will display. Results higher or lower than this range will display as > or < followed by a number.

The expected values listed in the instructions are the ranges expected for the majority of healthy persons (persons not diagnosed with any disease).

IMPORTANT TEST CONSIDERATIONS:

1. Make sure that you read and follow the instructions. If you are not sure how to run the test, call PTS, Inc. Customer Service for assistance before testing.
2. If any result is not as expected, questionable for any reason, above or below the measuring range or expected values range, always repeat the test.
3. Always consult your healthcare provider or medical practitioner and follow their advice.
4. Never make any changes in how you take your medication or make any medical decisions based on the results from this device unless instructed by your healthcare provider.

VIII. MEMORY

Test results are automatically stored in the analyzer's memory. The CardioChek® analyzer can store up to 30 results of each chemistry and at least 10 results of each control test. The analyzer allows review of the results in order from the most recent to the oldest. Each result is displayed with time and date. Results stored in memory are not deleted when the batteries are changed.

How to Review Results Stored in Memory:

1. Press either button to turn the analyzer ON. If the display reads INSTALL MEMO CHIP go to Step 2. If the display reads INSERT STRIP press Enter.
2. Press Next until MEMORY is displayed.
3. Press Enter. CHEM is displayed.
4. Press Enter, then Next to select the desired chemistry. (Note: Until the chemistry has been run at least once, the test name is not displayed.)
5. Press Enter to view the test result including time and date.
   a. To recall Quality Control results, press Next until EXIT is displayed. Press Enter. Press Next until CONTROL is displayed.
   b. Press Enter when the desired Quality Control test is displayed.
   c. For example, to review Lipid Panel results, from the CHEM display, press Next until LIPIDS is displayed, then Enter. The time and date will be displayed. Press Enter when the desired test time and date is displayed. Press Next to scroll through results.
6. To exit, press Next until the display reads EXIT, then press Enter. Repeat this step until you return to RUN TEST.

VIII. MEMORY, continued

How to Clear Results Stored in Memory:

1. Press either button to turn the analyzer ON. Wait for the display to read either INSTALL MEMO CHIP or INSERT STRIP.
2. Press Enter, then press Next until UTILITY is displayed. Press Enter.
3. Press Next until CLEAR MEMORY is displayed. Press Enter.
4. Press Next until the display reads CLR YES. Press Enter. The display will read ERASE, CLEARED, and then CLEAR MEMORY.
5. To exit, press Next until the display reads EXIT, then press Enter. Press Next until you return to RUN TEST.

IX. CARE AND CLEANING

Storage and Handling

- Handle the CardioChek® analyzer with care; do not drop.
- Do not store or operate the analyzer in direct light, such as sunlight, spotlight, under a lamp, or by a window.
- Do not expose the analyzer or any of the supplies or accessories to high humidity, extreme heat, cold, dust, or dirt. Store the analyzer at room temperature 68-80° F (20-27°C) and 20-80% Relative Humidity (RH). **Do not freeze.** If storage temperature is below 68° F (20° C) allow the analyzer to warm up to 68° F (20° C) at least 30 minutes to 1 hour before testing.
- Do not scratch or damage the surface of the check strip. Please read the test strip package insert for storage and handling information that applies to each test strip.

Cleaning Instructions

1. Locate the optical glass and the test strip insert opening.
2. Open an alcohol wipe/prep pad.
3. Fold the wipe and carefully wipe the optical glass and test strip guides clean. If the area is especially dirty, this may require additional wipes.
4. Immediately dry the optical glass completely with gauze. Make sure the glass is clean, dry, and completely free from any fingerprints, dust, or smudges. The glass must look clean when held at different angles.

If the exterior of the analyzer needs cleaning, wipe with a damp (not wet) alcohol wipe or dampen cloth with water or medical grade disinfectant (such as Sporocidin®) and wipe surfaces and the display area very carefully. Be careful not to get the test strip insert opening (where the test strip is inserted) wet. **Do not use bleach, window cleaner, or hydrogen peroxide.**

X. TROUBLESHOOTING

MESSAGE or ISSUE	PROBABLE CAUSE	WHAT TO DO
Desired language is not displayed.	Language has been set incorrectly.	Turn analyzer OFF. See Section III., Setup - How to Reset the Language.
The wrong date and/or time is displayed.	Date and time have not been set correctly.	See Section III., Setup to set the correct date and time.
FAILED is displayed during a check strip test.	Analyzer needs to be cleaned. Check strip is dirty or damaged.	Wipe the test strip insert opening with a clean, damp, and lint-free cloth. Use spare check strip. If check strip still fails, call Customer Service.
TOO MUCH LIGHT	Test is being performed in direct light or outside.	Test inside, away from windows, and away from direct lamp light.
MEMO ERR	MEMo Chip® is defective.	Use another MEMo Chip from the same lot.
TEST ERR	Insufficient sample has been added to test strip.	Test again with a new test strip and make sure the correct volume of sample is used.
LANGUAGE	Analyzer is new or language option has not been set.	Follow User Guide instructions to set language.
TEST NOT ALLOWED	Test selected by MEMo Chip installed cannot be run on your analyzer.	Check MEMo Chip and make sure that the correct MEMo Chip is inserted. Call Customer Service.

X. TROUBLESHOOTING, continued

MESSAGE or ISSUE	PROBABLE CAUSE	WHAT TO DO
LOW TEMP	Analyzer is below acceptable operating temperature.	Move to warmer environment and test after analyzer reaches proper temperature.
HI TEMP	Analyzer is above acceptable operating temperature.	Move to acceptable environment and test after analyzer reaches proper temperature.
INSTALL MEMO CHIP	MEMo Chip® is not properly inserted or is defective.	Insert same or new MEMo Chip properly.
EXPIRED LOT	Test strips are expired, wrong MEMo Chip is inserted, or analyzer date is not set properly.	Check test strip expiration date and make sure correct MEMo Chip is inserted. Check analyzer date setting – follow User Guide instructions.
CHANGE BATTERY	Batteries need to be replaced.	Replace both batteries with new high quality AAA batteries. (The analyzer will not run tests until batteries are replaced.)
TEST ABORTED	Test strip was not properly inserted or was removed before test was complete.	Test again with fresh test strip.

XI. UNEXPECTED RESULTS

High or low results that are incorrect may have serious medical consequences. If the result reads > (greater than) or < (less than) or results are not as expected, always repeat the test correctly with a new unused test strip. If a test result is displayed that is not expected, consult the following table. When using the CardioChek® test system to self-test, any result which is inconsistent with your medical history should immediately be reported to your physician or healthcare provider.

MESSAGE or ISSUE	PROBABLE CAUSE	WHAT TO DO
Results are not as expected.	Strips improperly stored.	Repeat test, using a different vial of strips. Run controls, confirm that results are in range.
	Batteries are defective.	Change batteries.
	The analyzer was improperly stored.	Make sure analyzer was not exposed to high or low temperatures or humidity and repeat test.
	Test strip insert opening is dirty.	Clean the test strip insert opening.
	MEMo Chip® and test strips are not the same lot number.	Use MEMo Chip and test strips with the same lot number.
A displayed result reads **<** (less than) a value.	Result is below the measuring range of the test.	If you have symptoms call a healthcare professional immediately. Repeat the test. Run controls and confirm that controls are in range.

XI. UNEXPECTED RESULTS, continued

MESSAGE or ISSUE	PROBABLE CAUSE	WHAT TO DO
A displayed result reads **>** (greater than) a value.	Result is above the measuring range of the test.	If you have symptoms call a healthcare professional immediately. Run test again. Run Quality Controls and confirm that Quality Controls are in range.
Display reads "_ _ _ _" or N/A.	Result is not available due to a missing value from a calculation, or a value is outside the measuring range.	Run test again. Run Quality Controls and confirm that Quality Controls are in range.
TRIGS TOO HIGH LDL N/A	Lipid Panel triglycerides test result was 400 mg/dL (4.52 mmol/L) or greater.	No action needed. LDL will not be calculated on samples with triglycerides of 400 mg/dL (4.52 mmol/L) or greater.

XII. SPECIFICATIONS

CardioChek® Analyzer

Calibration Curve: Input from MEMo Chip® per test strip lot
Battery: 2 AAA 1.5 volt alkaline
Operating Temperature Range: 68-80°F (20-27°C)
Humidity Range: Between 20 and 80% RH
Dimensions:

Width:	3.0 inches (7.62 cm)
Length:	5.5 inches (13.97 cm)
Height:	1.0 inches (2.54 cm)
Weight:	(without batteries): 4-6 oz. (113.4 - 170.1 g)

CardioChek test strips

Please read the instructions (package insert) included with the test strips for information specific to each test.

XIII. CONTACT INFORMATION

Help
For assistance with the CardioChek® test system, please contact:

Polymer Technology Systems, Inc. (PTS, Inc.)
+1-877-870-5610 (Toll-free inside USA)
+1-317-870-5610 (Direct)
+1-317-870-5608 (Fax)
E-mail: inforequest@cardiochek.com
Web site: www.cardiochek.com

XIV. WARRANTY

CardioChek® Analyzer Limited One Year Warranty

PTS, Inc. warrants to the original purchaser only, that the analyzer shall be free of any defects in materials or workmanship for a period of one year from the date of original purchase. Activation of this warranty shall be conditioned upon completion and return of the warranty registration card to PTS, Inc. If the equipment becomes inoperative during this time, PTS, Inc. will replace the equipment with equivalent equipment, at its option, at no cost to the purchaser. The warranty becomes void if the equipment is modified, improperly installed, or operation not in accordance with the User Guide, damaged by accident, or neglect, or if any parts are improperly installed or replaced by the user.

Note: Removing or loosening screws from the back of the analyzer voids all warranties. There are no user serviceable parts inside the case.

XV. EXPLANATION OF SYMBOLS

Symbols on the Analyzer and/or Analyzer Box:

Consult Instructions for Use

Store at/Temperature limitation

For *in vitro* diagnostic use

Serial Number

Manufacturer

Catalog Number

Authorized European Representative

This product fulfills the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices.

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The CardioChek®, CardioChek® PA and associated test strips are covered by one or more of the following patents: U.S. Patent Nos. 7,435,577, 7,625,721, 7,087,397, 7,214,504, 7,374,719, 7,494,818, 5,597,532, and D534444; Australian Patent No. 2002364609; Eurasian Patent No. 010414; Mexican Patent No. 267323; South African Patent Nos. 2004/4929 and 2006/06561; EP Patent No. 0750739 (DE, FR, GB, IT).

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